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AUG 19 2011

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the EVOLVE® TRIAD™ Plating System and EVOLVE® TRIAD™ Bone Screws.

A.1. Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd Arlington, TN 38002
Date:	May 20, 2011
Contact Person:	Angela Smith Regulatory Affairs Specialist (901) 867-4184
A.2. Proprietary Name:	**EVOLVE® TRIAD™ Plating System and EVOLVE® TRIAD™ Bone Screws**
Common Name:	Plate System and Bone Screws
Device Classification Regulation:	21 CFR 888.3030—Class II 21 CFR 888.3040—Class II
Device Product Code & Panel:	HRS: Plate, Fixation Bone HWC: Screw, Fixation Bone 87 Orthopedics
A.3. Predicate Device:	K102352—EVOLVE® EPS ORTHOLOC™ System K983495— Syntec-Taichung Non-Sterile Bone Screw Implants

A.3. Device Description

The EVOLVE® TRIAD™ Plating System consists of 9 plates, each belonging to 1 of 3 general categories—radial head, radial neck, and coronoid—based on the contouring of each plate. The radial head and radial neck plates feature poly-axial locking screw holes; the coronoid plates feature non-locking screw holes only.

All EVOLVE® TRIAD™ plates are made from Stainless Steel. The radial head and radial neck plates accept the 2.0mm ORTHOLOC™ Mini polyaxial locking screws and the 2.0mm EVOLVE® TRIAD™ non-locking bone screws. The coronoid plates accept the 2.0mm EVOLVE® TRIAD™ non-locking bone screws.

The design features of the EVOLVE® TRIAD™ Plating System and EVOLVE® TRIAD™ Bone Screws are substantially equivalent to the design features of the predicate devices EVOLVE® EPS ORTHOLOC™ System and the Syntec-Taichung Non-Sterile Bone Screw Implants.

A.4. Intended Use

Wright's EVOLVE® TRIAD™ Plating System is intended for fixation of fractures, osteotomies and non-unions of the olecranon, radius and ulna.

The ORTHOLOC™ Mini polyaxial locking screws are intended for use with Wright's plates manufactured from implant grade stainless steel that accept ORTHOLOC™ Mini polyaxial locking screws.

The EVOLVE® TRIAD™ Bone Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device, including the clavicle, scapula, long bones (ulna, radius and humerus) and small bones (metacarpals, metatarsals, and phalanges).

A.5. Technological Characteristics Comparison

The EVOLVE® TRIAD™ Plating System and EVOLVE® TRIAD™ Bone Screws and the legally marketed predicate devices EVOLVE® EPS ORTHOLOC™ System and the Syntec Bone Screw Implants have similar indications, utilize similar instrumentation, are manufactured from Stainless Steel, and are included in the size range of the legally marketed predicate.

B.1. Substantial Equivalence – Non-Clinical Evidence

Substantial equivalence is shown through worst-case plate analysis screw and construct torque to failure, polyaxial performance, and pull out testing. The results of the test show that the subject EVOLVE® TRIAD™ Plating System and EVOLVE® TRIAD™ Bone Screws can be expected to perform at least as well as the legally marketed predicate EVOLVE® EPS ORTHOLOC™ System and the Syntec-Taichung Non-Sterile Bone Screw Implants.

The safety and effectiveness of the subject EVOLVE® TRIAD™ Plating System and EVOLVE® TRIAD™ Bone Screws is adequately supported by the substantial equivalence information, materials information, and comparison of design characteristics provided within the Premarket Notification.

B.2. Substantial Equivalence – Clinical Evidence

N/A

B.3. Substantial Equivalence - Conclusions

Substantial equivalence is shown through worst-case plate analysis and torque to failure, polyaxial performance, and pull out/pull through testing. The subject plates are similar to the predicate plates in material, anatomical design and selection, materials, and similar in indications, and instrumentation utilized. The subject screws are similar in indication for use, size range and material to the predicate, and differ in diameter, driver type. No new types of safety and effectiveness questions can be expected. From the evidence given in the Premarket Notification, the subject devices can be expected to perform at least as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Wright Medical Technology, Inc.
% Ms. Angela Smith
Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

AUG 19 2011

Re: K111432
Trade/Device Name: EVOLVE® Triad™ Plating System and
EVOLVE® Triad™ Bone Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: May 20, 2011
Received: May 23, 2011

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111432 (pg 1/1)

Device Name: EVOLVE® TRIAD™ Plating System and EVOLVE® TRIAD™ Bone Screws

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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